

# EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-689 (CFC)
	)	
APOTEX INC. AND APOTEX CORP.,	)	
	)	
Defendants.	)	
	)	
	)	

**FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Vanda Pharmaceuticals Inc. (“Vanda”) for its First Amended Complaint against Defendants Apotex Inc. and Apotex Corp. alleges as follows:

**I. THE PARTIES**

1. Plaintiff Vanda is a Delaware corporation with its principal place of business at 2200 Pennsylvania Ave. NW, Suite 300E, Washington, DC 20037. Vanda is a pharmaceutical company that focuses on the development and commercialization of new medicines to address unmet medical needs, including HETLIOZ® (tasimelteon oral capsules), for the treatment of Non-24-Hour Sleep-Wake Disorder (“Non-24”).

2. On information and belief, Apotex Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

3. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

4. On information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc.

5. On information and belief Apotex Corp. is the designated U.S. agent for Apotex Inc. in accordance with 21 C.F.R. § 314.50(a) in connection with Abbreviated New Drug Application No. 211607 (the “Apotex ANDA”).

6. On information and belief, Apotex Corp. is a generic pharmaceutical company that distributes and sells generic pharmaceutical products in the State of Delaware and throughout the United States that are manufactured by Apotex Inc. (Apotex Inc. and Apotex Corp. are collectively referred to herein as “Apotex” unless otherwise specified).

## **II. NATURE OF THE ACTION**

7. This is an action arising under the patent laws of the United States (Title 35, U.S. Code, §§ 100, *et seq.*) based upon Apotex’s infringement of one or more claims of Vanda’s U.S. Patent Nos. RE46,604 (“the RE604 patent”); 9,060,995 (“the ’995 patent”); 9,539,234 (“the ’234 patent”); 9,549,913 (“the ’913 patent”); 9,730,910 (“the ’910 patent”); and 9,855,241 (“the ’241 patent”) (collectively “the Asserted Patents”), which, in relevant part, generally relate to the use of tasimelteon in the treatment of Non-24, and based upon Apotex’s infringement of one or more claims of Vanda’s U.S. Patent No. 10,071,977 (“the ’977 patent”), which, in relevant part, generally relates to purified tasimelteon and processes for preparing the same.

8. Vanda is the holder of approved New Drug Application No. 205,677 for Hetlioz® (tasimelteon) capsules, 20 mg, which was approved by the Food and Drug Administration (“FDA”) on January 31, 2014, for the treatment of Non-24 (“HETLIOZ® NDA”).

9. Tasimelteon is the active ingredient in HETLIOZ®.

10. On April 3, 2018, Vanda received written notice of the Apotex ANDA and Paragraph IV Certification as to the Asserted Patents (“Notice Letter”), along with an enclosed statement of Apotex’s alleged factual and legal bases for stating that the Asserted Patents are invalid, unenforceable, and/or will not be infringed by Apotex’s generic version of Hetlioz® (“Detailed Statement”).

11. On information and belief, Apotex Inc. and Apotex Corp. acted in concert to prepare and submit the Apotex ANDA and the Detailed Statement purports to reference Confidential Information of both Apotex Inc. and Apotex Corp.

12. On information and belief, Apotex filed the Apotex ANDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (the “FFDCA”), to obtain approval to commercially manufacture and sell generic tasimelteon capsules in its 20 mg strength for the treatment of Non-24 (“Apotex’s ANDA Product”).

13. On information and belief, Apotex made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) that, in its opinion and to the best of its knowledge, the Asserted Patents are invalid, unenforceable, and/or that certain claims will not be infringed by Apotex’s ANDA Product.

14. On information and belief, Apotex made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the ’977 patent is invalid, unenforceable, and/or that certain claims will not be infringed by Apotex’s ANDA Product.

15. This action is being commenced within 45 days of receipt of Apotex’s Notice Letter.

16. Vanda received written notice of Apotex's Paragraph IV Certification as to the '977 patent on November 16, 2018 ("Supplemental Notice Letter"), along with an enclosed statement of Apotex's alleged factual and legal bases for stating that the '977 patent is invalid, unenforceable, and/or will not be infringed by Apotex's ANDA Product ("Supplemental Detailed Statement").

17. Apotex's Supplemental Detailed Statement does not provide any factual bases for stating that the '977 patent is unenforceable.

18. Apotex has infringed one or more claims of each of the Asserted Patents and the '977 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Apotex ANDA with a Paragraph IV Certification and seeking FDA approval of the Apotex ANDA prior to the expiration of the Asserted Patents or any extensions thereof.

19. Apotex has infringed one or more claims of each of the Asserted Patents and the '977 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Apotex ANDA seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States generic tasimelteon for the treatment of Non-24 prior to the expiration of the Asserted Patents and the '977 patent or any extensions thereof. Apotex will infringe one or more claims of each of the Asserted Patents and the '977 patent under 35 U.S.C. § 271(a), (b), (c), or (g) should it engage in, induce, or contribute to the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 prior to the expiration of the Asserted Patents and the '977 patent or any extensions thereof.

### III. JURISDICTION

20. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has subject matter jurisdiction over Vanda's patent infringement claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

21. This Court has personal jurisdiction over Apotex Corp. because Apotex Corp. is incorporated in the State of Delaware.

22. On information and belief, Apotex Corp. is registered to conduct business within the State of Delaware (File No. 2293995). *See* <https://icis.corp.delaware.gov/Ecorp/EntitySearch/NameSearch.aspx> (accessed on April 6, 2018).

23. On information and belief, Apotex Corp. maintains as a registered agent for service of process is Corporate Creations Network, Inc., with an address at 3411 Silverside Road #104, Tatnall Building, Wilmington, Delaware 19810.

24. This Court has personal jurisdiction over Apotex Inc. under Fed. R. Civ. P. 4(k) because, on information and belief, Apotex Inc. is organized under the laws of Canada.

25. This Court has personal jurisdiction over Apotex Inc. because at least one of the provisions under Del. Code Ann. tit. 10, § 3104, is satisfied. On information and belief, Apotex satisfies at least § 3104(c)(1) (“[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) (“[c]ontracts to supply services or things in this State”), § 3104(c)(3) (“[c]auses tortious injury in the State by an act or omission in this State), and § 3104(c)(4) “[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State”).

26. This Court also has personal jurisdiction over Apotex Inc. because this suit arises out of and relates to Apotex Inc.'s activities, in concert with Apotex Corp., that are, and will be, directed to Delaware. On information and belief, following any FDA approval of the Apotex ANDA, Apotex Inc., in concert with Apotex Corp., will market and sell Apotex's ANDA Product that is the subject of the infringement claims in this action in the State of Delaware and throughout the United States, including this judicial District.

27. On information and belief, Apotex Inc., directly and through its subsidiaries, affiliates, or agents, including Apotex Corp., are in the business of manufacturing generic pharmaceuticals that it distributes or has distributed in the State of Delaware and throughout the United States.

28. Apotex Inc. and Apotex Corp., acting in concert, have committed, or aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Vanda, which manufactures HETLIOZ® for sale and use throughout the United States, including in this judicial District.

29. On information and belief, and as indicated by the Notice Letter and Supplemental Notice Letter, Apotex Inc., in concert with Apotex Corp., prepared and filed ANDA No. 211607 with the intention of seeking to market generic tasimelteon nationwide, including within this judicial District.

30. On information and belief, Apotex plans to market and sell generic tasimelteon in the State of Delaware, list generic tasimelteon on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursement for sales of the ANDA Product in the State of Delaware, either directly or through one or more of Apotex's subsidiaries, agents, and/or alter egos.

31. On information and belief, Apotex knows and intends that its proposed generic tasimelteon product will be distributed and sold in Delaware and will thereby displace sales of HETLIOZ®, causing injury to Vanda. Apotex intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed generic tasimelteon product.

32. This Court also has personal jurisdiction over Apotex Inc. by virtue of, *inter alia*, its activities, in concert with Apotex Corp. (e.g., filing the Apotex ANDA seeking approval to market generic tasimelteon prior to the expiration of the Asserted Patents along with a Paragraph IV Certification regarding the Asserted Patents and sending notice of that Paragraph IV Certification), which were purposefully directed to the State of Delaware. Vanda is incorporated in Delaware, and thus the consequences of Apotex Inc.'s actions were (and will be) suffered in Delaware. Apotex Inc. knew or should have known that Vanda is a Delaware corporation and thus Apotex Inc. knew or should have known that the consequences of its actions were (and will be) suffered in Delaware.

33. This Court also has personal jurisdiction over Apotex Inc. because Apotex Inc.'s contacts within this judicial District are continuous and systematic. On information and belief, Apotex Inc., in concert with Apotex Corp., develops, manufactures, seeks approval for, and sells FDA-approved generic pharmaceutical drugs, which are being marketed, distributed, and sold in Delaware and throughout the United States. Thus, on information and belief, Apotex Inc. does substantial business in Delaware, derives substantial revenue from Delaware, and engages in other persistent courses of conduct in Delaware. These continuous and systematic contacts, including, but not limited to, those described above and below, are more than sufficient for this Court to exercise personal jurisdiction over Apotex, Inc.



34. On information and belief, Apotex Inc. maintains continuous and systematic contacts with Delaware through its U.S. subsidiary Apotex Corp., which is incorporated in Delaware.

35. Furthermore, on information and belief, Apotex Corp. and Apotex Inc. have admitted or consented to, or not contested, the jurisdiction of this Court and/or have availed themselves of the rights, benefits, and privileges of this Court by asserting claims and counterclaims in prior District of Delaware actions. *See, e.g., ViiV Healthcare Co. v. Apotex Inc. and Apotex Corp.*, C.A. No. 17-1634-VAC, D.I. 9 (D. Del.); *Teva Pharm. Int'l GmbH v. Apotex Inc. and Apotex Corp.*, C.A. No. 17-cv-01164-GMS, D.I. 17 (D. Del.); *Onyx Therapeutics, Inc. v. Apotex Inc. and Apotex Corp.*, C.A. No. 1:17-cv-01202-LPS, D.I. 10 (D. Del.).

#### IV. VENUE

36. Venue is proper in this judicial District under 28 U.S.C. § 1391(b) and (c) and § 1400(b) because Apotex Corp. is incorporated in the State of Delaware and Apotex Inc. is incorporated in Canada and may be sued in any judicial district in the United States in which Apotex Inc. is subject to the court's personal jurisdiction. *See Koninklijke KPN N.V. v. Kyocera Corp.*, C.A. No. 17-cv-87-LPS, 2017 WL 6447873, \*3 & n.5 (D. Del. Dec. 18, 2017).

#### V. THE PATENTS-IN-SUIT

**(U.S. PATENT NOS. RE46,604; 9,060,995; 9,539,234; 9,549,913; 9,730,910; 9,855,241;  
10,071,977)**

37. The allegations above are incorporated herein by reference.

38. The Asserted Patents cover the use of tasimelteon to treat patients with Non-24.

39. As explained in the Asserted Patents, "Non-24 occurs when individuals, primarily blind with no light perception, are unable to synchronize their endogenous circadian

pacemaker to the 24-hour light/dark cycle. Without light as a synchronizer, and because the period of the internal clock is typically a little longer than 24 hours, individuals with Non-24 experience their circadian drive to initiate sleep drifting later and later each day. Individuals with Non-24 have abnormal night sleep patterns, accompanied by difficulty staying awake during the day.” As also explained in the Asserted Patents, “[t]he ultimate treatment goal for individuals with Non-24 is to entrain or synchronize their circadian rhythms into an appropriate phase relationship with the 24-hour day so that they will have increased sleepiness during the night and increased wakefulness during the daytime.”

40. The Asserted Patents explain that “Tasimelteon is a circadian regulator which binds specifically to two high affinity melatonin receptors, Mel1a (MT1R) and Mel1b (MT2R). These receptors are found in high density in the suprachiasmatic nucleus of the brain (SCN), which is responsible for synchronizing our sleep/wake cycle.”

41. The '977 patent covers purified tasimelteon and processes for obtaining the same.

42. As explained in the '977 patent, “the synthesis of tasimelteon can result in a plurality of impurities following the end step synthesis” and that some such impurities “are potentially genotoxic and must be controlled to ppm levels in order for the bulk GMP [Good Manufacturing Practices] tasimelteon to be suitable for formulation into bulk pharmaceutical composition and subsequently distributed into pharmaceutical dosage units.”

#### **U.S. Patent No. RE46,604**

43. Vanda is the owner of all rights, title, and interest in the RE604 patent, entitled “Treatment of Circadian Rhythm Disorders.” The USPTO duly and legally issued the RE604 patent (a reissue patent) on November 14, 2017, to Marlene M. Dressman, John J. Feeney, Louise W. Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned

to Vanda. A true and correct copy of the RE604 patent is attached to this First Amended Complaint as Exhibit A.

44. The RE604 patent generally claims methods of treating Non-24 by orally administering 20 mg of tasimelteon once daily before bedtime. As an example, claim 1 of the RE604 patent claims: “A method of entraining a patient suffering from Non-24 to a 24 hour sleep-wake cycle in which the patient awakens at or near a target wake time following a daily sleep period of approximately 7 to 9 hours, and maintaining said 24 hour sleep-wake cycle said method comprising: treating the patient by orally administering to the patient 20 mg of tasimelteon once daily before a target bedtime.”

45. The RE604 patent also claims methods of treating Non-24 by avoiding the use of tasimelteon in combination with a CYP1A2 inhibitor, such as fluvoxamine. As an example, claim 6 of the RE604 patent claims “The method of claim 1 further comprising: (i) first determining if the patient is also being treated with a CYP1A2 inhibitor, and (ii) if the patient is being treated with a CYP1A2 inhibitor, reducing the dose of the CYP1A2 inhibitor.” And claim 7 of the RE604 patent claims: “The method of claim 6 wherein the CYP1A2 inhibitor is ciprofloxacin, fluvoxamine, or verapamil.”

**U.S. Patent No. 9,060,995**

46. Vanda is the owner of all rights, title, and interest in the '995 patent, entitled “Treatment of Circadian Rhythm Disorders.” The USPTO duly and legally issued the '995 patent on June 23, 2015, to Marlene M. Dressman, John J. Feeney, Louise W. Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned to Vanda. A true and correct copy of the '995 patent is attached to this First Amended Complaint as Exhibit B.

47. The '995 patent generally claims a method of treating Non-24 by avoiding the use of tasimelteon in combination with fluvoxamine. The sole claim, claim 1, claims “A

method of entraining a light perception impaired patient suffering from Non-24-Hour Sleep-Wake Disorder to a 24-hour sleep-wake cycle in which the patient awakens at or near a target wake time following a daily sleep period of approximately 7 to 9 hours, wherein the patient is being treated with fluvoxamine, the method comprising: (A) discontinuing the fluvoxamine treatment and then (B) orally treating the patient with 20 mg of tasimelteon once daily before a target bedtime, thereby avoiding the use of tasimelteon in combination with fluvoxamine.”

**U.S. Patent No. 9,539,234**

48. Vanda is the owner of all rights, title and interest in the '234 patent, entitled “Treatment of Circadian Rhythm Disorders.” The USPTO duly and legally issued the '234 patent on January 10, 2017, to Marlene M. Dressman, John J. Feeney, Louise W. Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned to Vanda. A true and correct copy of the '234 patent is attached to this First Amended Complaint as Exhibit C.

49. The '234 patent generally claims methods of treating Non-24 by avoiding the use of tasimelteon in combination with a strong CYP1A2 inhibitor. For example, claim 3, which depends from claim 1, claims “The method of claim 1, that comprises treating the patient for Non-24-Hour Sleep-Wake Disorder wherein the patient is light perception impaired (LPI).”

**U.S. Patent No. 9,549,913**

50. Vanda is the owner of all rights, title, and interest in the '913 patent, entitled “Treatment of Circadian Rhythm Disorders.” The USPTO duly and legally issued the '913 patent on January 24, 2017, to Marlene M. Dressman, Louise W. Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned to Vanda. A true and correct copy of the '913 patent is attached to this First Amended Complaint as Exhibit D.

51. The '913 patent generally claims methods of entraining a patient's cortisol circadian rhythm to a 24-hour circadian rhythm and maintaining that 24-hour circadian rhythm

by orally administering to the patient tasimelteon once daily before a target bedtime. For example, claim 1 claims “A method of entraining a patient’s cortisol circadian rhythm to a 24-hour circadian rhythm and maintaining said 24-hour circadian rhythm, the method comprising: treating the patient by orally administering to the patient tasimelteon once daily before a target bedtime.” For example, claim 4 claims “The method of claim 1, wherein the patient suffers from Non-24-Hour Sleep-Wake Disorder.”

**U.S. Patent No. 9,730,910**

52. Vanda is the owner of all rights, title, and interest in the ’910 patent, entitled “Treatment of Circadian Rhythm Disorders.” The USPTO duly and legally issued the ’910 patent on August 15, 2017, to Marlene M. Dressman, John J. Feeney, Louise W. Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned to Vanda. A true and correct copy of the ’910 patent is attached to this First Amended Complaint as Exhibit E.

53. The ’910 patent generally claims methods of treating Non-24 by avoiding the use of tasimelteon in combination with rifampin. For example, claim 2, which depends from claim 1, claims “The method of claim 1 that comprises treating the patient for Non-24-Hour Sleep-Wake Disorder.” Claim 1 claims “A method of treating a patient for a circadian rhythm disorder wherein the patient is being treated with rifampicin, the method comprising: (A) discontinuing the rifampicin treatment and then (B) treating the patient with tasimelteon, thereby avoiding the use of tasimelteon in combination with rifampicin and also thereby avoiding reduced exposure to tasimelteon caused by induction of CYP3A4 by rifampicin.”

54. Rifampicin is also known as rifampin.

**U.S. Patent No. 9,855,241**

55. Vanda is the owner of all rights, title, and interest in the ’241 patent, entitled “Treatment of Circadian Rhythm Disorders.” The USPTO duly and legally issued the

'241 patent on January 2, 2018, to Marlene M. Dressman, Louise W. Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned to Vanda. A true and correct copy of the '241 patent is attached to this First Amended Complaint as Exhibit F.

56. The '241 patent generally claims methods of synchronizing a patient's abnormal cortisol circadian rhythm and abnormal melatonin circadian rhythm with a natural day/night cycle by treating the patient by orally administering to the patient an effective amount of tasimelteon once daily before a target bedtime. For example, claim 4, which depends from claim 1, claims "The method of claim 1, wherein the patient suffers from Non-24-Hour Sleep-Wake Disorder." Claim 1 claims "A method of synchronizing a patient's abnormal cortisol circadian rhythm and abnormal melatonin circadian rhythm with a natural day/night cycle, the method comprising: treating the patient by orally administering to the patient an effective amount of tasimelteon once daily before a target bedtime."

**U.S. Patent No. 10,071,977**

57. Vanda is the owner of all rights, title, and interest in the '977 patent, entitled "Highly Purified Pharmaceutical Grade Tasimelteon." The USPTO duly and legally issued the '977 patent on September 11, 2018 to Deepak Phadke, Natalie M. Platt, and Ravi K. Pandrapragada, as inventors, which was assigned to Vanda. A true and correct copy of the '977 patent is attached to this First Amended Complaint as Exhibit G.

58. The '977 patent generally claims purified tasimelteon and processes for preparing the same. For example, claim 1 claims "A process for synthesizing highly purified, pharmaceutical grade tasimelteon. Claim 24 claims "Purified tasimelteon wherein the tasimelteon does not contain" certain enumerated impurities "at a concentration of greater than about 0.15%."

## **VI. COUNT I**

### **(INFRINGEMENT OF THE RE604 PATENT)**

59. The allegations above are incorporated herein by reference.

60. Apotex filed the Apotex ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the RE604 patent and any extensions thereof.

61. Apotex's Notice Letter states that Apotex filed the Apotex ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the RE604 patent. The Notice Letter represents that Apotex's ANDA was submitted with a Paragraph IV Certification that the RE604 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Apotex's ANDA Product.

62. Apotex thus has actual knowledge of the RE604 patent.

63. The FDA-approved HETLIOZ® Label instructs physicians that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

64. The HETLIOZ® Label further instructs physicians that "[t]he recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

65. The HETLIOZ® Label further instructs physicians to "[a]void use of HETLIOZ in combination with fluvoxamine or other strong CYP1A2 inhibitors because of a potentially large increase in tasimelteon exposure and greater risk of adverse reactions."

66. On information and belief, the Apotex ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

67. Thus, the use of HETLIOZ® and any generic tasimelteon for the treatment of Non-24 is covered by the RE604 patent, and Vanda has the right to enforce the RE604 patent and sue for infringement thereof.

68. The RE604 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for HETLIOZ® in its 20 mg strength.

69. On information and belief, the Apotex ANDA essentially copies the HETLIOZ® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, and/or suggests physicians to infringe at least claims 1, 6, and 7 of the RE604 patent.

70. On information and belief, Apotex's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claims 1, 6, and 7 of the RE604 patent.

71. Apotex has infringed the RE604 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Apotex ANDA to FDA seeking to obtain approval for generic tasimelteon in its 20 mg strength for the treatment of Non-24, which is covered by one or more claims of the RE604 patent, prior to the expiration of the RE604 patent.

72. Apotex Corp. and Apotex Inc. are jointly and severally liable for the infringement of one or more claims of the RE604 patent. On information and belief, Apotex Corp. and Apotex Inc.'s participation in, contribution to, inducement of, aiding or abetting the submission of the Apotex ANDA and its Paragraph IV Certification to FDA constitutes direct, contributory, or induced infringement of one or more claims of the RE604 patent under 35 U.S.C. § 271(e)(2)(A).



73. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Apotex ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the RE604 patent, including at least claims 1, 6, and 7 under 35 U.S.C. § 271(a), (b), and/or (c).

74. Vanda seeks entry of an order requiring that Apotex amend its Paragraph IV Certification in the Apotex ANDA to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) (“Paragraph III Certification”) as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

75. Vanda seeks entry of an order declaring that Apotex has infringed the RE604 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

76. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Apotex ANDA be a date that is not earlier than the expiration of the RE604 patent or any later expiration of exclusivity for the RE604 patent to which Vanda becomes entitled.

77. Vanda will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the RE604 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

78. On information and belief, Apotex’s statement of the factual and legal bases for its opinion regarding the invalidity and noninfringement of the RE604 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys’ fees pursuant to 35 U.S.C. § 285.

79. To the extent Apotex commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

**VII. COUNT II**  
**(INFRINGEMENT OF THE '995 PATENT)**

80. The allegations above are incorporated herein by reference.

81. Apotex filed the Apotex ANDA under § 505(j) of the FDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the '995 patent and any extensions thereof.

82. Apotex's Notice Letter states that Apotex filed the Apotex ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the '995 patent. The Notice Letter represents that the Apotex ANDA was submitted with a Paragraph IV Certification that the '995 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Apotex's ANDA Product.

83. Apotex thus has actual knowledge of the '995 patent.

84. The FDA-approved HETLIOZ® Label instructs physicians that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

85. The HETLIOZ® Label further instructs physicians that "[t]he recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

86. The HETLIOZ® Label further instructs physicians to "[a]void use of HETLIOZ in combination with fluvoxamine or other strong CYP1A2 inhibitors because of a potentially large increase in tasimelteon exposure and greater risk of adverse reactions."

87. On information and belief, the Apotex ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

88. Thus, the use of HETLIOZ® and any generic tasimelteon for the treatment of Non-24 is covered by the '995 patent, and Vanda has the right to enforce the '995 patent and sue for infringement thereof.

89. The '995 patent is listed in the Orange Book for HETLIOZ® in its 20 mg strength.

90. On information and belief, the Apotex ANDA essentially copies the HETLIOZ® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, and/or suggests physicians to infringe claim 1 of the '995 patent.

91. On information and belief, Apotex's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe claim 1 of the '995 patent.

92. Apotex has infringed the '995 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Apotex ANDA to FDA seeking to obtain approval for generic tasimelteon in its 20 mg strength for the treatment of Non-24, which is covered by claim 1 of the '995 patent, prior to the expiration of the '995 patent.

93. Apotex Corp. and Apotex Inc. are jointly and severally liable for the infringement of one or more claims of the '995 patent. On information and belief, Apotex Corp. and Apotex Inc.'s participation in, contribution to, inducement of, aiding or abetting the submission of the Apotex ANDA and its Paragraph IV Certification to FDA constitutes direct, contributory, or induced infringement of one or more claims of the '995 patent under 35 U.S.C. § 271(e)(2)(A).

94. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Apotex ANDA would infringe directly or contribute to or induce the infringement of claim 1 of the '995 patent under 35 U.S.C. § 271(a), (b), and/or (c).

95. Vanda seeks entry of an order requiring that Apotex amend its Paragraph IV Certification in the Apotex ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

96. Vanda seeks entry of an order declaring that Apotex has infringed the '995 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

97. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Apotex ANDA be a date that is not earlier than the expiration of the '995 patent or any later expiration of exclusivity for the '995 patent to which Vanda becomes entitled.

98. Vanda will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing or contributing to infringement of claim 1 of the '995 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

99. On information and belief, Apotex's statement of the factual and legal basis for its opinion regarding the invalidity and noninfringement of the '995 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

100. To the extent Apotex commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

## **VIII. COUNT III**

### **(INFRINGEMENT OF THE '234 PATENT)**

101. The allegations above are incorporated herein by reference.

102. Apotex filed the Apotex ANDA under § 505(j) of the FDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the '234 patent, and any extensions thereof.

103. Apotex's Notice Letter states that Apotex filed the Apotex ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the '234 patent. The Notice Letter represents that the Apotex ANDA was submitted with a Paragraph IV Certification that the '234 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Apotex's ANDA Product.

104. Apotex thus has actual knowledge of the '234 patent.

105. The FDA-approved HETLIOZ® Label instructs physicians that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

106. The HETLIOZ® Label further instructs physicians that "[t]he recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

107. The HETLIOZ® Label further instructs physicians to "[a]void use of HETLIOZ in combination with fluvoxamine or other strong CYP1A2 inhibitors because of a potentially large increase in tasimelteon exposure and greater risk of adverse reactions," and to "[a]void use of HETLIOZ in combination with strong CYP1A2 inhibitors because of increased exposure."

108. On information and belief, the Apotex ANDA seeks approval for a 20mg tasimelteon oral capsule for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

109. Thus, the use of HETLIOZ® and any generic tasimelteon for the treatment of Non-24 is covered by the '234 patent, and Vanda has the right to enforce the '234 patent and sue for infringement thereof.

110. The '234 patent is listed in the Orange Book for HETLIOZ® in its 20 mg strength.

111. On information and belief, the Apotex ANDA essentially copies the HETLIOZ® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, and/or suggests physicians to infringe at least claim 3 of the '234 patent.

112. On information and belief, Apotex's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claim 3 of the '234 patent.

113. Apotex has infringed the '234 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Apotex ANDA to FDA seeking to obtain approval for generic tasimelteon in its 20 mg strength, for the treatment of Non-24, which is covered by one or more claims of the '234 patent, prior to the expiration of the '234 patent.

114. Apotex Corp. and Apotex Inc. are jointly and severally liable for the infringement of one or more claims of the '234 patent. On information and belief, Apotex Corp. and Apotex Inc.'s participation in, contribution to, inducement of, aiding or abetting the submission of the Apotex ANDA and its Paragraph IV Certification to FDA constitutes direct, contributory, or induced infringement of one or more claims of the '234 patent under 35 U.S.C. § 271(e)(2)(A).

115. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Apotex ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the '234 patent, including at least claim 3, under 35 U.S.C. § 271(a), (b), and/or (c).

116. Vanda seeks entry of an order requiring that Apotex amend its Paragraph IV Certification in the Apotex ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

117. Vanda seeks entry of an order declaring that Apotex has infringed the '234 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

118. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Apotex ANDA be a date that is not earlier than the expiration of the '234 patent or any later expiration of exclusivity for the '234 patent to which Vanda becomes entitled.

119. Vanda will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '234 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

120. On information and belief, Apotex's statement of the factual and legal basis for its opinion regarding the invalidity and noninfringement of the '234 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

121. To the extent Apotex commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

**IX. COUNT IV  
(INFRINGEMENT OF THE '913 PATENT)**

122. The allegations above are incorporated herein by reference.

123. Apotex filed the Apotex ANDA under § 505(j) of the FDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the '913 patent and any extensions thereof.

124. Apotex's Notice Letter states that Apotex filed the Apotex ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the '913 patent. The Notice Letter represents that the Apotex ANDA was submitted with a Paragraph IV Certification that the '913 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Apotex's ANDA Product.

125. Apotex thus has actual knowledge of the '913 patent.

126. The FDA-approved HETLIOZ® Label instructs physicians that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

127. The HETLIOZ® Label further instructs physicians that "[t]he recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

128. On information and belief, the Apotex ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

129. Thus, the use of HETLIOZ® and any generic tasimelteon for the treatment of Non-24 is covered by the '913 patent, and Vanda has the right to enforce the '913 patent and sue for infringement thereof.



130. The '913 patent is listed in the Orange Book for HETLIOZ® in its 20 mg strength.

131. On information and belief, the Apotex ANDA essentially copies the HETLIOZ® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, and/or suggests physicians to infringe at least claims 1 and 4 of the '913 patent.

132. On information and belief, Apotex's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claims 1 and 4 of the '913 patent.

133. Apotex has infringed the '913 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Apotex ANDA to FDA seeking to obtain approval for generic tasimelteon, in its 20 mg strength, for the treatment of Non-24, which is covered by one or more claims of the '913 patent, prior to the expiration of the '913 patent.

134. Apotex Corp. and Apotex Inc. are jointly and severally liable for the infringement of one or more claims of the '913 patent. On information and belief, Apotex Corp. and Apotex Inc.'s participation in, contribution to, inducement of, aiding or abetting the submission of the Apotex ANDA and its Paragraph IV Certification to FDA constitutes direct, contributory, or induced infringement of one or more claims of the '913 patent under 35 U.S.C. § 271(e)(2)(A).

135. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Apotex ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the '913 patent, including at least claims 1 and 4, under 35 U.S.C. § 271(a), (b), and/or (c).

136. Vanda seeks entry of an order requiring that Apotex amend its Paragraph IV Certification in the Apotex ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

137. Vanda seeks entry of an order declaring that Apotex has infringed the '913 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

138. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Apotex ANDA be a date that is not earlier than the expiration of the '913 patent or any later expiration of exclusivity for the '913 patent to which Vanda becomes entitled.

139. Vanda will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '913 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

140. On information and belief, Apotex's statement of the factual and legal basis for its opinion regarding the invalidity and noninfringement of the '913 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

141. To the extent Apotex commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

## **X. COUNT V**

### **(INFRINGEMENT OF THE '910 PATENT)**

142. The allegations above are incorporated herein by reference.

143. Apotex filed the Apotex ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the '910 patent and any extensions thereof.

144. Apotex's Notice Letter states that Apotex filed the Apotex ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the '910 patent. The Notice Letter represents that the Apotex ANDA was submitted with a Paragraph IV Certification that the '910 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Apotex's ANDA Product.

145. Apotex thus has actual knowledge of the '910 patent.

146. The FDA-approved HETLIOZ® Label instructs physicians that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

147. The HETLIOZ® Label further instructs physicians that "The recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

148. The HETLIOZ® Label further instructs physicians to "Avoid use of HETLIOZ in combination with rifampin or other CYP3A4 inducers because of a potentially large decrease in tasimelteon exposure with reduced efficacy," and to "Avoid use of HETLIOZ in combination with rifampin or other CYP3A4 inducers, because of decreased exposure."

149. On information and belief, the Apotex ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

150. Thus, the use of HETLIOZ® and any generic tasimelteon for the treatment of Non-24 is covered by the '910 patent, and Vanda has the right to enforce the '910 patent and sue for infringement thereof.

151. The '910 patent is listed in the Orange Book for HETLIOZ® in its 20 mg strength.

152. On information and belief, the Apotex ANDA essentially copies the HETLIOZ® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, and/or suggests physicians to infringe at least claim 2 of the '910 patent.

153. On information and belief, Apotex's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claim 2 of the '910 patent.

154. Apotex has infringed the '910 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Apotex ANDA to FDA seeking to obtain approval for generic tasimelteon, in its 20 mg strength, for the treatment of Non-24, which is covered by one or more claims of the '910 patent, prior to the expiration of the '910 patent.

155. Apotex Corp. and Apotex Inc. are jointly and severally liable for the infringement of one or more claims of the '910 patent. On information and belief, Apotex Corp. and Apotex Inc.'s participation in, contribution to, inducement of, aiding or abetting the submission of the Apotex ANDA and its Paragraph IV Certification to FDA constitutes direct, contributory, or induced infringement of one or more claims of the '910 patent under 35 U.S.C. § 271(e)(2)(A).

156. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Apotex ANDA would infringe directly or contribute to or

induce the infringement of one or more claims of the '910 patent, including at least claim 2, under 35 U.S.C. § 271(a), (b), and/or (c).

157. Vanda seeks entry of an order requiring that Apotex amend its Paragraph IV Certification in the Apotex ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

158. Vanda seeks entry of an order declaring that Apotex has infringed the '910 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

159. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Apotex ANDA be a date that is not earlier than the expiration of the '910 patent or any later expiration of exclusivity for the '910 patent to which Vanda becomes entitled.

160. Vanda will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '910 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

161. On information and belief, Apotex's statement of the factual and legal basis for its opinion regarding the invalidity and noninfringement of the '910 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

162. To the extent Apotex commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

## **XI. COUNT VI**

### **(INFRINGEMENT OF THE '241 PATENT)**

163. The allegations above are incorporated herein by reference.

164. Apotex filed the Apotex ANDA under § 505(j) of the FDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the '241 patent and any extensions thereof.

165. Apotex's Notice Letter states that Apotex filed the Apotex ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the '241 patent. The Notice Letter represents that the Apotex ANDA was submitted with a Paragraph IV Certification that the '241 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Apotex's ANDA Product.

166. Apotex thus has actual knowledge of the '241 patent.

167. The FDA-approved HETLIOZ® Label instructs physicians that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

168. The HETLIOZ® Label further instructs physicians that "[t]he recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

169. On information and belief, the Apotex ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

170. Thus, the use of HETLIOZ® and any generic tasimelteon for the treatment of Non-24 is covered by the '241 patent, and Vanda has the right to enforce the '241 patent and sue for infringement thereof.

171. The '241 patent is listed in the Orange Book for HETLIOZ® in its 20 mg strength.

172. On information and belief, the Apotex ANDA essentially copies the HETLIOZ® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, and/or suggests physicians to infringe at least claim 4 of the '241 patent.

173. On information and belief, Apotex's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claim 4 of the '241 patent.

174. Apotex has infringed the '241 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Apotex ANDA to FDA seeking to obtain approval for generic tasimelteon, in its 20 mg strength, for the treatment of Non-24, which is covered by one or more claims of the '241 patent, prior to the expiration of the '241 patent.

175. Apotex Corp. and Apotex Inc. are jointly and severally liable for the infringement of one or more claims of the '241 patent. On information and belief, Apotex Corp. and Apotex Inc.'s participation in, contribution to, inducement of, aiding or abetting the submission of the Apotex ANDA and its Paragraph IV Certification to FDA constitutes direct, contributory, or induced infringement of one or more claims of the '241 patent under 35 U.S.C. § 271(e)(2)(A).

176. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Apotex ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the '241 patent, including at least claim 4, under 35 U.S.C. § 271(a), (b), and/or (c).

177. Vanda seeks entry of an order requiring that Apotex amend its Paragraph IV Certification in the Apotex ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

178. Vanda seeks entry of an order declaring that Apotex has infringed the '241 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

179. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Apotex ANDA be a date that is not earlier than the expiration of the '241 patent, or any later expiration of exclusivity for the '241 patent to which Vanda becomes entitled.

180. Vanda will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '241 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

181. On information and belief, Apotex's statement of the factual and legal basis for its opinion regarding the invalidity and noninfringement of the '241 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

182. To the extent Apotex commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

## **XII. COUNT VII**

### **(INFRINGEMENT OF THE '977 PATENT)**

183. The allegations above are incorporated herein by reference.

184. Apotex filed the Apotex ANDA under § 505(j) of the FDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the '977 patent and any extensions thereof.

185. Apotex's Supplemental Notice Letter states that Apotex filed the ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg



strength for the treatment of Non-24 before the expiration of the '977 patent. The Supplemental Notice Letter represents that an Amendment to the Apotex ANDA was submitted with a Paragraph IV Certification that the '977 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Apotex's ANDA Product.

186. The '977 patent is listed in the Orange Book for HETLIOZ® in its 20 mg strength and ANDA applicants generally must amend or supplement ANDAs to submit an appropriate patent certification for patents that issue after submission of the ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)(II) and 21 C.F.R. § 314.94(a)(12)(viii)(C)(ii).

187. Apotex thus has actual knowledge of the '977 patent.

188. Vanda has the right to enforce the '977 patent and sue for infringement thereof.

189. On information and belief, Apotex has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States products which are made by a process or using purified tasimelteon patented by the '977 patent.

190. On information and belief, Apotex's preparations include, but are not limited to, the development of Apotex's ANDA Product, systematically attempting to meet the applicable regulatory requirements for approval of Apotex's ANDA Product, and engaging in litigation to manufacture, offer to sell, sell, use, and/or import Apotex's ANDA Product prior to the expiration of the '977 patent.

191. On information and belief, Apotex intends to use the processes and purified tasimelteon claimed in the '977 patent to prepare the tasimelteon in Apotex's ANDA Product.

192. On information and belief, the tasimelteon in Apotex's ANDA Product is intact and without material change from the tasimelteon resulting from the processes of the '977 patent.

193. On information and belief, the tasimelteon resulting from the processes of the '977 patent is an essential part of Apotex's ANDA Product.

194. On information and belief, the tasimelteon resulting from the processes of the '977 patent is not a trivial or non-essential component of another product.

195. On information and belief, Apotex's ANDA Product is covered by one or more claims of the '977 patent.

196. On information and belief, Apotex's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claims 1, 18, 22, 23, and 24 of the '977 patent.

197. Apotex has infringed and will infringe the '977 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Apotex ANDA, and any amendments thereto, to FDA seeking to obtain approval for generic tasimelteon covered by one or more claims of the '977 patent, prior to the expiration of the '977 patent.

198. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Apotex ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the '977 patent, including at least claims 1, 18, 22, 23, and 24, under 35 U.S.C. § 271(a), (b), (c), and/or (g).

199. On information and belief, Apotex will induce others to infringe and/or contribute to the infringement of at least claims 1, 18, 22, 23, and 24 of the '977 patent under 35 U.S.C. § 271(b) and/or (c) by, among other things, actively and knowingly aiding and abetting

others to infringe, including, but not limited to the manufacturer of Apotex's ANDA products, or its Active Pharmaceutical Ingredient ("API"), or other subsequent purchasers, distributors, or users thereof, which product or its manufacture constitutes direct infringement of at least claims 1, 18, 22, 23, and 24 of the '977 patent.

200. On information and belief, Apotex's aiding and abetting includes Apotex's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of Apotex's ANDA Product.

201. On information and belief, Apotex will induce others to infringe and/or contribute to the infringement of at least claims 1, 18, 22, 23, and 24 of the '977 patent under § 271(b) and/or (c) by making, using, selling, offering to sell, and/or importing Apotex's ANDA Product and/or the API thereof.

202. On information and belief, subsequent purchasers, distributors or users thereof will also directly infringe at least claims 1, 18, 22, 23, and 24 of the '977 patent.

203. On information and belief Apotex will infringe at least claim 1 of the '977 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell, or using Apotex's ANDA Product or the API for Apotex's ANDA Product.

204. On information and belief, Apotex's ANDA Product and/or the API for Apotex's ANDA Product is not materially changed by subsequent process.

205. On information and belief, Apotex's ANDA Product and the API for Apotex's ANDA Product are not a trivial or non-essential component of another product.

206. Vanda seeks entry of an order requiring that Apotex amend its Paragraph IV Certification in the Apotex ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

207. Vanda seeks entry of an order declaring that Apotex has infringed the '977 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

208. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Apotex ANDA be a date that is not earlier than the expiration of the '977 patent, or any later expiration of exclusivity for the '977 patent to which Vanda becomes entitled.

209. Vanda will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '977 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

210. On information and belief, Apotex's statement of the factual and legal basis for its opinion regarding the invalidity and noninfringement of the '977 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

211. To the extent Apotex commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

### **PRAYER FOR RELIEF**

WHEREFORE, Vanda respectfully requests that this Court enter judgment in its favor against Apotex and grant the following relief:

A. an adjudication that Apotex has infringed directly, contributed to, or induced the infringement of one or more claims of the RE604 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Apotex ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the RE604 patent;

B. an adjudication that Apotex has infringed directly, contributed to, or induced the infringement of one or more claims of the '995 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Apotex ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the '995 patent;

C. an adjudication that Apotex has infringed directly, contributed to, or induced the infringement of one or more claims of the '234 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Apotex ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the '234 patent;

D. an adjudication that Apotex has infringed directly, contributed to, or induced the infringement of one or more claims of the '913 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Apotex ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the '913 patent;

E. an adjudication that Apotex has infringed directly, contributed to, or induced the infringement of one or more claims of the '910 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Apotex ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the '910 patent;

F. an adjudication that Apotex has infringed directly, contributed to, or induced the infringement of one or more claims of the '241 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Apotex ANDA to obtain approval for the commercial

manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the '241 patent;

G. an adjudication that Apotex has infringed directly, contributed to, or induced the infringement of one or more claims of the '977 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Apotex ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the '977 patent;

H. a declaration that Apotex will infringe directly, contribute to, or induce the infringement of one or more claims of the RE604 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the RE604 patent;

I. a declaration that Apotex will infringe directly, contribute to, or induce the infringement of one or more claims of the '995 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the '995 patent;

J. a declaration that Apotex will infringe directly, contribute to, or induce the infringement of one or more claims of the '234 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the '234 patent;

K. a declaration that Apotex will infringe directly, contribute to, or induce the infringement of one or more claims of the '913 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the '913 patent;

L. a declaration that Apotex will infringe directly, contribute to, or induce the infringement of one or more claims of the '910 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the '910 patent;

M. a declaration that Apotex will infringe directly, contribute to, or induce the infringement of one or more claims of the '241 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the '241 patent;

N. a declaration that Apotex will infringe directly, contribute to, or induce the infringement of one or more claims of the '977 patent under 35 U.S.C. § 271(a), (b), (c), and/or (g) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the '977 patent;

O. an order requiring that Apotex amend its Paragraph IV Certification to a Paragraph III certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

P. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Apotex ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the RE604 patent or any later period of exclusivity to which Vanda is or may become entitled;

Q. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Apotex ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the '995 patent or any later period of exclusivity to which Vanda is or may become entitled;

R. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Apotex ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the '234 patent or any later period of exclusivity to which Vanda is or may become entitled;

S. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Apotex ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the '913 patent or any later period of exclusivity to which Vanda is or may become entitled;

T. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Apotex ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the '910 patent or any later period of exclusivity to which Vanda is or may become entitled;

U. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Apotex ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the '241 patent or any later period of exclusivity to which Vanda is or may become entitled;

V. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Apotex ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the '977 patent or any later period of exclusivity to which Vanda is or may become entitled;

W. a permanent injunction enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the RE604 patent, or contributing to or inducing



anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Apotex ANDA;

X. a permanent injunction enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '995 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Apotex ANDA;

Y. a permanent injunction enjoining Apotex, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '234 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Apotex ANDA;

Z. a permanent injunction enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '913 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Apotex ANDA;

AA. a permanent injunction enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '241 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Apotex ANDA;

BB. a permanent injunction enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '910 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Apotex ANDA;

CC. a permanent injunction enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '977 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Apotex ANDA;

DD. an order enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the RE604 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Apotex ANDA while the litigation is pending;

EE. an order enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '995 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Apotex ANDA while the litigation is pending;

FF. an order enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '913 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Apotex ANDA while the litigation is pending;

GG. an order enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '234 patent, contributing to, or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Apotex ANDA while the litigation is pending;

HH. an order enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '241 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Apotex ANDA while the litigation is pending;

II. an order enjoining Apotex, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '977 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any

current or future versions of the product described in the Apotex ANDA while the litigation is pending;

JJ. an assessment of pre-judgment and post-judgment interest and costs against Apotex, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284;

KK. an award to Vanda of its attorneys' fees incurred in connection with this lawsuit pursuant to 35 U.S.C. § 285; and

LL. such other and further relief as this Court may deem just and proper.

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